

GAU 1633

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants: Graham P. Allaway et al.

Serial No.: 09/460,216

Group Art Unit: 1633

Filed : December 13, 1999

For METHOD FOR PREVENTING HIV-1 INFECTION OF CD4+ CELLS



1185 Avenue of the Americas
New York, New York 10036
January 19, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**.

1. U.S. Patent No. 5,021,409 issued June 4, 1991 to Murrer et al.;
2. U.S. Patent No. 5,126,433, issued 6/30/92 to Maddon et al.;
3. U.S. Patent No. 5,440,021, issued August 5, 1995 to Chuntharapai et al.;
4. U.S. Patent No. 5,504,003, issued April 2, 1996 to Li et al.;
5. Alkhatib, G., et al., (1996), CC CKR5: A RANTES, MIP-1 α , MIP-1 β Receptor As A Fusion Cofactor For Macrophage-tropic HIV-1, Science 272: 1955-1958;
6. Alkhatib et al., (1997), HIV-1 Coreceptor Activity Of CCR5

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And Its Inhibition By Chemokines: Independence From G Protein Signaling And Importance Of Coreceptor Downmodulation, Virology 234: 340-348 (**Exhibit 1**);

7. Arenzana-Selsdedos, F., et al., (1996), HIV Blocked By Chemokine Antagonist, Nature 383: 400;
8. Berger et al., (1999), Chemokine Receptors As HIV-1 Coreceptors: Roles In Viral Entry, Tropism, And Disease, Ann. Rev. Immunol. 17: 657-700 (**Exhibit 2**);
9. Bleul, C.C., et al., (1996), The Lymphocyte Chemoattractant SDF-1 Is A Ligand For LESTR/Fusion And Blocks HIV-1 Entry, Nature 382: 829-832;
10. Brenner, T.J., et al., (1991), Relation Between HIV-1 Syncytium Inhibition Antibodies And Clinical Outcome In Children, The Lancet 337: 1001-1003;
11. Choe, H., et al., (1996), The β -chemokine Receptors CCR3 And CCR5 Facilitate Infection By Primary HIV-1 Isolates, Cell 85: 1135-1148;
12. Cocchi, F., et al., (1995), Identification Of RANTES, MIP-1 α , And MIP-1 β As The Major HIV-suppressive Factors Produced By CD8⁺ T Cells, Science 270: 1811-1815;
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15. DeClercq, E., et al., (1994), Highly Potent And Selective Inhibition Of Human Immunodeficiency Virus By The Bicyclam Derivative JM3100, Antimicrobial Agents and Chemotherapy 38: 668-674;
16. DeClerq, E., (1995), Antiviral Therapy For Human Immunodeficiency Virus Infections, J. Clin. Microbiol. Rev. 8(2): 200-239 (**Exhibit 3**);
17. Deng et al., (1996), Identification Of A Major Co-receptor For Primary Isolates Of HIV-1, Nature 381: 661-666;
18. Doranz et al., (1996), A Dual-Tropic Primary HIV-1 Isolate That Uses Fusin And The β -Chemokine Receptors CKR-5, CKR-3, and CKR-2b As Fusin Cofactors, Cell 85: 1149-1158 (**Exhibit 4**);
19. Doranz et al., (1997), A Small-Molecule Inhibitor Directed Against The Chemokine Receptor CXCR4 Prevents Its Use As An HIV-1 Coreceptor, J. Exp. Med. 186(8): 1395-1400 (**Exhibit 5**);
20. Dragic, T., et al., (1996), HIV-1 Entry Into CD4+ Cells Is Mediated By The Chemokine Receptor CC-CKR-5, Nature 381: 667-673;
21. Fahey et al., (1992), Status Of Immune-based Therapies In HIV Infection And AIDS, Clin. Exp. Immunol. 88: 1-5;
22. Feng et al, (1996), HIV-1 Entry Cofactor: Functional cDNA Cloning Of A Seven-transmembrane, G Protein-coupled

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25. Gong, J., et al., (1996), RANTES and MCP-3 Antagonists Bind Multiple Chemokine Receptors, J.Biol.Chem. 271:10521-10527;
26. Hattori, T., et al., (1989), Involvement Of Trypsin-related Cellular Protease(s) In Human Immunodeficiency Virus Type 1 Infection, FEBS Letters 248: 48-52;
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28. Jones, S.A., et al., (1997), Chemokine Antagonists That Discriminate Between Interleukin-8 Receptors, J. Biol. Chem. 272: 16166-16169;
29. Klotman et al., (1995), Transgenic Models Of HIV-1, AIDS 9(4): 313-324 (**Exhibit 6**);
30. Levy, (1996), Controlling HIV Pathogenesis: The Role Of The Noncytotoxic Anti-HIV Response Of CD8+ T Cells, Immunology Today 17: 217-224 (**Exhibit 7**);
31. Litwin et al., (1996), Human Immunodeficiency Virus Type 1 Membrane Fusin Mediated By A Laboratory-adapted Strain And A Primary Isolate Analyzed By Resonance Energy Transfer,

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J.Virol. 70(9): 6437-6441 (**Exhibit 8**);

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33. Moser, B., et al., (1993), Interleukin-8 Antagonists Generated By N-terminal Modification, J. Biol. Chem. 268: 7125-7128;
34. Oberlin, E., et al., (1996), The CXC Chemokine SDF-1 Is The Ligand For LESTR/Fusion And Prevents Infection By T-cell-line-adapted HIV-1, Nature 382: 833-835;
35. Oellerich, M., (1984), Enzyme-Immunoassay: A Review, J. Clin. Chem. Clin. Biochem. 22(12): 895-904;
36. Raport, C.J., et al., (1996), New Members Of The Chemokine Receptor Gene Family, J. Leuk. Biol. 59: 18-23;
37. Samson, M., et al., (1996), Molecular Cloning And Functional Expression Of A New Human CC-chemokine Receptor Gene, Biochemistry 35: 3362-3367 (**Exhibit 9**);
38. Scarlatti et al., (1997), In Vivo Evolution Of HIV-1 Co-receptor Usage And Sensitivity To Chemokine-mediated Suppression, Nature Medicine 3(11): 1259-1265 (**Exhibit 10**);
39. Simmons, G., et al., (1997), Potent Inhibition Of HIV-1 Infectivity In Macrophages And Lymphocytes By A Novel CCR5 Antagonist, Science 276: 276-279;
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Binding, J. Immunol. 149(11): 3596-3604 (**Exhibit 11**);

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42. Wells, T., et al., (1996), Selectivity And Antagonism Of Chemokine Receptors, J. Leuk. Biol. 59: 53-60;
43. Wu, L., et al., (1996), CD4-induced Interaction Of Primary HIV-1 gp120 Glycoproteins With The Chemokine Receptor CCR-5, Nature 384: 179-183;
44. Wu, L., et al., (1997), CCR5 Levels And Expression Pattern Correlate With Infectability By Macrophage-tropic HIV-1, In Vitro, J. Exp. Med. 185: 1681-1691; and
45. Zhang, Y.J., et al., (1994), Structure/Activity Analysis Of Human Monocyte Chemoattractant Protein-1 (MCP-1) By Mutagenesis, J. Biol. Chem. 269: 15918-15924.

The subject application is a continuation of and claims the benefit under 35 U.S.C. §120 of PCT International Application No. PCT/US98/12331, filed June 12, 1998, which is a continuation-in-part of and claims the benefit under 35 U.S.C. §120 of U.S. Serial No. 08/876,078, filed June 13, 1997, which is a continuation-in-part of and claims the benefit under 35 U.S.C. §120 of U.S. Serial No. 08/831,823, filed April 2, 1997.

The above listed references 3-5, 7, 9-12, 20, 24-26, 28, 32-34, 36, 39, and 41-45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on December 21, 1998 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. Above listed references 1, and 14-15 were submitted to and considered by the

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United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on January 21, 2000 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. Also, above listed references 13, 21, 23, 27 and 39 were cited by the United States Patent and Trademark Office in an Office Action dated December 21, 1998 in connection with 08/831,823, filed April 2, 1997. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

The above listed references 5, 7, 9, 11-12, 20, 24-25, 28, 32-34, 36, 39, and 41-45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on October 8, 1998 in connection with U.S. Serial No. 08/876,078, filed June 13, 1997. Above listed references 17, 21-23, 27 and 35 were cited by the United States Patent and Trademark Office in an Office Action dated March 23, 1998 in connection with U.S. Serial No. 08/876,078, filed June 13, 1997. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

A Search Report was issued on October 15, 1998 in connection with PCT International Application No. PCT/US98/12331, filed June 12, 1998. A copy of the Search Report is attached hereto as **Exhibit B**. Above listed references 6, 12-13, 17, 19, 21-23, 27, 35, 38-39 and 41 were cited in the Search Report. Additionally, above listed reference 8 was cited in a Preliminary Examination Report issued January 27, 2000 in connection with PCT International

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Application No. PCT/US98/12331, filed June 12, 1998. A copy of the Preliminary Examination Report is attached hereto as **Exhibit C**. References 12, 39 and 41 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on December 21, 1998 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. Reference 13 was cited by the United States Patent and Trademark Office in an Office Action dated December 21, 1998 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. References 17, 21-23, 27 and 35 were cited by the United States Patent and Trademark Office in an Office Action dated March 23, 1998 in connection with U.S. Serial No. 08/876,078, filed June 13, 1997. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120. References 6, 8, 19 and 38 are attached hereto as **Exhibits 1, 2, 5 and 10**, respectively.

The above listed references 12, 22, 24-25, 30, 33, 36-37, 42 and 45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on March 10, 1997 in connection with U.S. Serial No. 08/663,616, filed June 14, 1996. References 12, 24-25, 33, 36, 42 and 45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on December 21, 1998 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. Reference 22 was cited by the United States Patent and Trademark Office in an Office Action dated March 23, 1998 in connection with U.S. Serial No. 08/876,078, filed June 13, 1997. Accordingly, under 37 C.F.R. §1.98(d) copies of references 12, 22, 24-25, 33, 36, 42, and 45 are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United

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States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120. References 30 and 37 are attached hereto as **Exhibits 7 and 9**, respectively.

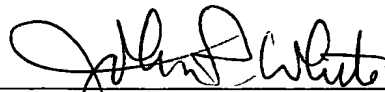
The above listed references 3, 5, 7, 9-12, 15-16, 18, 20, 24, 26, 28-29, 31-34, 36 and 39-45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on January 4, 1999, in connection with U.S. Serial No. 08/874,618, filed June 13, 1997. Above listed references 2, 13, 17, 20-23 and 27 were cited by the United States Patent and Trademark Office in an Office Action dated September 2, 1998 in connection with U.S. Serial No. 08/874,618, filed June 13, 1997. References 3-5, 7, 9-12, 20, 24, 26, 28, 32-34, 36, 39 and 41-45 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on December 21, 1998 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. Reference 15 was submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on January 21, 2000 in connection with U.S. Serial No. 08/831,823, filed April 2, 1997. Accordingly, under 37 C.F.R. §1.98(d) copies of references 3-5, 7, 9-12, 15, 20, 24, 26, 28, 32-34, 36, 39 and 41-45 are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120. References 16, 18, 29, 31 and 40 are attached hereto as **Exhibits 3, 4, 6, 8 and 11**, respectively.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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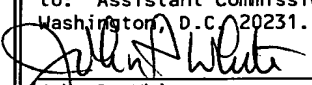
Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.


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